IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Bachmann, et al.	Examiner:	B. Kifle
Serial No.:	10/762,107	Group Art Unit:	1624
Filed:	January 21, 2004		
Entitled:	Farnesyl Dibenzodiazepinone, and Processes for its Production	Conf. No.:	4987

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF DR. LESTER A. MITSCHER UNDER 37 C.F.R. §1.132

I declare:

1. I, Lester A. Mitscher received a Ph.D. from Wayne State University, Detroit, Michigan in 1958. I am currently a University of Kansas Distinguished Professor in the Department of Medicinal Chemistry, of which I served as Chairman from 1975 to 1991.

2. I am not an inventor on the above-noted patent application. My areas of expertise and research include extensive experience in the biology and medicinal chemistry of microbial natural products. I have served as Chairman of the Biological and Natural Products Study Section of the National Institutes of Health, Chairman of the Hematology and Chemotherapy Study Section of the American Cancer Society, Chairman of the Medicinal Chemistry Division of the American Chemical Society, and I am an elected Fellow of the American Association for the Advancement of Science and the International Union of Pure and Applied Chemistry. I have served or am presently serving on the editorial boards of 19 scientific journals, including, among others, The Journal of Antibiotics, The Journal of Medicinal Chemistry, Natural Product Letters, Natural Products Research, The Journal of Natural Products, and Bioactive Natural Products. I have sat or am presently sitting on the Scientific Advisory Board of 13 separate pharmaceutical/biopharmaceutical corporations, and I have or presently serve as a consultant to 41 different pharmaceutical/biopharmaceutical corporations. A copy of my *curriculum vitae* is

attached.

3. I am an inventor on 19 United States patents and my research has been published in over 250 peer-reviewed articles and publications.

4. I have performed on one occasion paid consulting work for Ecopia BioSciences Inc. in the area of chemical synthetic alternatives to biofermentation for the production of bacterial natural products. I have agreed to provide this Declaration and in this regard I will be receiving remuneration from Ecopia BioSciences Inc. for the time devoted to this service.

5. I have read the above-referenced patent application (USSN 10/762,107), and the Office Action issued April 26, 2006 in the above-noted patent application, and I understand that the Examiner has rejected claims 1, 2 and 20-25 for alleged lack of novelty with regard to the disclosure in U.S. Patent No. 5,541,181, issued to Ohkuma et al. ("Ohkuma et al."), in view of the later-published paper by Igarashi et al. (2005), J. Antibiotics (Tokyo) 58(5): 350-352. More specifically, the Examiner stated the following at page 2 of the Office Action:

> The claims read on the compound made by the microorganism, strain M990-6, identified as being a species of *Micromonospora*. The reference depicts the structure of the compound isolated incorrectly. However, the later published correction by Igarashi et al. (in J. Antibiot. 58 (5): 350-352 (2005)) revised the structure of the reference.
>
> This anticipation rejection is made on the compound produced by the same microorganism and has the same NMR spectrum as in the prior art (with the difference of solvent peaks). Therefore, the compound claimed was first produced by Ohkuma et al. and the claims read thereon.

6. I have carefully read the Ohkuma et al. patent and the above-referenced Igarashi et al. (2005) Journal of Antibiotics paper entitled "Revision of the Structure Assigned to the Antibiotic BU-4664L from Micromonopora [sic]," which were cited in the Office Action.

7. Based on my analyses of the Ohkuma et al. patent and the Igarashi et al. paper, I **cannot agree** with the assertions by Igarashi et al. that the structure of BU-4664L as reported by Ohkuma et al. in U.S. Patent 5,541,181 is incorrect and that the structure of BU-4664L should be revised so as to be identical with the structure for the molecule obtained by Igarashi et al. from *Micromonospora* sp. strain TP-A0860, as drawn in the Igarashi et al. reference. In summary, the

Igarashi et al. reference is **not persuasive for at least the following two reasons**:

> **A)** There are significant differences in the NMR spectral data as between the compound obtained by Igarashi et al. from *Micromonospora* sp. strain TP-A0860 and the compound BU-4664L isolated by Ohkuma et al. and characterized in U.S. Patent 5,541,181, and it cannot be definitively concluded that the compounds are identical. These differences are not limited to the solvent peaks – the NMR spectral data provided in U.S. Patent 5,541,181 and the NMR spectral data provided in the Igarashi et al. reference are not interchangeable (*i.e.* the NMR spectral data are indicative of two structurally distinct molecules); and
>
> **B)** There is no scientific/experimental evidence put forward in the Igarashi et al. reference to support Igarashi et al.'s proposed re-drawing of the structure of BU-4664L - Igarashi et al. did not perform any direct comparison between the compound (BU-4664L) isolated by Okhuma et al. from the M990-6 *Micromonospora* strain and the compound that they (Igarashi et al.) isolated from the *Micromonospora* sp. strain TP-A0860. There is no scientific proof to support the assertion put forward by Igarashi et al. regarding the identity of the two compounds.

My rationale with respect to each of these points is set out as follows:

> **Point A) The NMR spectral data presented in Igarashi et al. for the compound obtained by Igarashi et al. from *Micromonospora* sp. strain TP-A0860, when compared to the NMR spectral data reported by Ohkuma et al. for BU-4664L, do not support Igarashi et al.'s proposal that the compounds are identical.**

(i) At the outset, having regard to the chemical structure of BU-4664L as drawn in the Okhuma et al. patent and to the chemical structure of the compound obtained by Igarashi et al. from *Micromonospora* sp. strain TP-A0860 and depicted in the Igarashi et al. reference, it is evident that the two compounds are close analogs that differ from one another in the orientation of the hydroxyl anthranilic acid moiety that is fused with the remaining portion of each molecule. As such, an ordinarily skilled artisan would **expect** substantial similarities in certain of the spectral properties as between two compounds having the chemical structures reported in the Ohkuma et al. patent and in the Igarashi et al. paper: the molecular ions in the mass spectra (MS) of the two substances would be the same – they are merely isomers with the same elemental composition; the ultraviolet (UV) spectra would be closely similar because the substitution patterns in the chromophoric regions of the molecules are very similar; the infra-red (IR) spectra would also be closely similar because the functional groups attached to the basic ring system are very similar; and given that the farnesyl side chain is identical in the two formulae, identical or

nearly identical proton (^{1}H) and carbon (^{13}C) nuclear magnetic resonance (NMR) signals would be expected **with respect to the side chain**. With regard to the IR data of Igarashi et al., these are limited to frequencies associated with only two functional groups (both of which were present in the Ohkuma et al. molecule), and no fingerprint region absorptions are listed nor is the matrix listed in which the spectrum was run. I have compared the MS, UV and IR spectral, and the farnesyl side chain ^{1}H and ^{13}C NMR data presented in Okhuma et al. to the like data presented in Igarashi et al. reference, and I observe that the numerical values in both data sets are identical or closely similar. Regardless of the similarity or identity of these data as between the molecules, there are **also** *significant differences* in the NMR spectral data reported by Ohkuma et al. and Igarashi et al. (discussed below).

(ii) Of the various methods that may be employed for comparing the structures of chemical compounds, a comparison of the ^{13}C nuclear magnetic resonance spectra are the most likely to reveal differences in molecular connectivity. As between two molecules, inconsistencies (outside of ordinary tolerance ranges) in NMR data values are indicative of structural differences between the molecules. In relation to BU-4664L (as drawn in the Okhuma et al. patent) and the compound obtained by Igarashi et al. from *Micromonospora* sp. strain TP-A0860, such differences would be most likely to occur in NMR signals arising from the tricyclic ring system carbons. I have conducted a comparison of the ^{13}C NMR signals listed in Table 7 of the Ohkuma et al. patent and the ^{13}C NMR signals listed in Table 1 of the Igarashi et al. reference (which I note are those for the compound obtained by Igarashi et al. from *Micromonospora* sp. strain TP-A-0860, despite the Table 1 legend describing "NMR assignment for BU-4664L (DMSO-d_6)"), and I observe a very significant inconsistency in the NMR spectral data as between the two molecules. The two data sets are copied below for convenience, with the ^{13}C NMR values from the Igarashi et al. reference aligned so as to best fit with those provided in the Okhuma et al. patent:

^{13}C NMR spectra for corresponding carbon atoms of the two structures as reported by the two sets of authors:

Carbon Atom (as numbered by Okhuma et al.)	NMR Signal Value Reported by Okhuma et al. for BU-4664L		Carbon Atom (as numbered by Igarashi et al.)	NMR Signal Value Reported by Igarashi et al. for the TP-A0860 Molecule
1	122.2		1	122.3
2	120.8		2	120.4
3	116.3		3	116.5
4	145.4		4	145.5
4a	134.8		9a	134.9
5a	**134.5**		11a	**124.8**
6	100.4		7	100.4
7	152.9		8	153.0
8	99.4		9	99.4
9	147.5		6	147.6
9a	124.8		5a	124.8
11	167.5		11	167.6
11a	141.1		4a	141.1

I have performed a best fit alignment for the two data sets (*i.e.* that being a strongest comparison for a reassigned alignment for the ^{13}C NMR signals provided in the Okhuma et al. patent for BU-4664L and those for the ^{13}C NMR signals for the molecule obtained by Igarashi et al. from *Micromonospora* sp. strain TP-A0860), and the best fit alignment reveals a 9.7 ppm misalignment for the signal from carbon 5a of BU-4664L and carbon 11a of the Igarashi et al. molecule. These are precisely the positions most likely to differ between the two molecules because these positions represent carbon atoms where rings are fused (differently) together. The peak assignments made in the Igarashi et al. reference are supported by long range spectroscopic

measurements and in the table above are not changed from those the authors made.

(iii) The difference of 9.7 ppm in the resonances between carbons 5a in BU-4664L (134.5 ppm) and 11a in the Igarashi et al. compound (124.8 ppm) is **significant and striking**. If these spectra are reported correctly, and I can find no reason to believe they were not, **the differences are not consistent with the conclusion, or even an assertion, that the two compounds are identical**. If the compounds isolated by Igarashi et al. and by Ohkuma et al. are identical, there should be no significant differences in the ^{13}C NMR spectral data between the compounds. In fact, these compounds do not have the same NMR spectra. I note that the spectra in both instances were measured in the same solvent system, hexadeuterated dimethyl sulfoxide, and at the same field strength, 100 MHz. A person of skill in the art would expect that precise peak positions might vary from one instrument to another, but that person would expect that these variations to amount to no more than a few tenths of a part per million (as for example, might account for the differences between the peak positions for carbon 1 in each data set; note also that in four positions the values *are* identical between the data sets – this further supports the significance and reality of the 9.7 ppm difference in the reported peak positions at carbons 5a and 11a, respectively). Based on the evidence (i.e. the ^{13}C NMR spectral data) presented in the Okhuma et al. patent and Igarashi et al reference, I find that **the differences** in the ^{13}C NMR spectral data between Igarashi et al. and Ohkuma et al. **are significant** and are **NOT limited to solvent peaks**. Given these differences, I cannot agree with the assertion made by Igarashi et al. that the structure of BU-4664L as determined by Okhuma et al. is incorrect and that the structure of BU-4664L should be revised so as to be the same as that for the molecule obtained by Igarashi et al. and described in the Igarashi et al. reference.

I further note that whereas the Ohkuma et al. data lists two signals in the 134 ppm range (134.8 and 134.5), Igarashi et al. lists only one (134.9). Thus, even if one were to challenge the assignments to specific carbons in the table, there are telling differences in the spectra and not just in peak assignments.

(iv) I have also conducted a comparison of the NMR spectral data presented in the Okhuma et al. patent and that presented in the Igarashi et al. reference in relation to the determination of the placement of the farnesyl side chain. In order to conclude that both

molecules are identical, Igarashi et al. had to re-assign the signals reported in the Ohkuma et al. reference. I note that the strongest evidence for the placement of the farnesyl side chain on the molecule described in the Igarashi et al. reference paper is a long range spectral correlation observed by Igarashi et al. between the terminal methylene moiety of the farnesyl side chain and the amide carbonyl (C-11) of the molecule they isolated from their strain TP-A0860. I refer to the wording provided at page 351, lines 28-32 in the left hand column of the Igarashi et al. reference in this regard. Regarding the BU-4664L molecule characterized in the Okhuma et al. patent, I note that long range coupling was observed by Ohkuma et al. (column 14, lines 41-50) from the same farnesyl methylene protons in the tri-O-methyl derivative, but not in correlation with the carbonyl carbon. I refer to passage provided at column 14, lines 41-50 of the Okhuma et al. patent in this regard. I can find no basis in fact to question the veracity of the long range coupling data presented by each of these groups. The discrepancy in the long range coupling data, on a comparison between Igarashi et al. and Okhuma et al., is significant and supports a conclusion that **the molecules are not identical**.

(v) In my expert opinion, it is far more likely and reasonable to conclude, given the NMR spectral differences alone, that the compounds do not have the same structure (*i.e.* BU-4664L has the structure as reported in the Okhuma et al. patent, and the compound obtained characterized by Igarashi et al. from *Micromonospora* sp. strain TP-A0860 has the structure as reported in the Igarashi et al. reference). This is further supported by the lack of a direct comparison.

Point B) No experiments were conducted by Igarashi et al. wherein they performed a direct (*i.e.* actual) comparison between the compound that they isolated from *Micromonospora* sp. strain TP-A-0860 and the authentic BU-4664L compound, as isolated from *Micromonospora* sp. strain M990-6 by Okhuma et al.

(i) The basic scientific approach for examining differences between two molecules is to directly compare their properties under the same experimental conditions. I have reviewed the Igarashi et al. reference, and nowhere is it disclosed or implied in this reference that this scientifically convincing test was performed. As such, **there is no scientific or factual basis presented in the Igarashi et al reference** from which one can validly conclude that the structure for the compound BU-4664L reported by Okhuma et al. is incorrect and that BU-4664L is the same compound as that obtained by Igarashi et al. from *Micromonospora* sp. strain TP-

A0860. Instead, the position taken is an assertion, which is insufficiently supported by the evidence reported. Assertions of belief differ from facts.

(ii) Igarashi et al. did not directly test BU-4664L in their studies. The Ohkuma et al. patent names, as "BU-4664L", a compound produced by the *Micromonospora* sp. strain M990-6 and reports the isolation of the compound and its structural formula (under the reference character (A)) in column 1 of the patent. Having reviewed the Igarashi et al. reference, I observe that these authors did not test a compound produced by this bacterial strain. I note that the respective strains are not the same microorganism, but only belong to the same genus. Rather, these authors describe the isolation and characterization of a compound produced by a different strain of bacteria, TP-A0860, and their findings provide for a compound that has a similar, yet different, structure than that of BU-4664L. The Igarashi et al. authors acknowledged in their paper on page 351 (lines 32-33 of the left hand column) that "*direct comparison with the authentic compound of BU-4664L was not possible*" (emphasis added). In conducting my review of the Igarashi et al. reference, I observe that **all** of the experimental data reported in the Igarashi et al. reference **relate only to the compound isolated by Igarashi et al.** None of the experimental data presented by Igarashi et al. relate to the authentic BU-4664L, despite the legends provided by these authors for their Figures 1 and 2 and Table 1 (e.g. Table 1, "NMR assignment for BU-4664L (DMSO-d_6)") and frequent references made to BU-4664L by the authors throughout the text of their publication.

(iii) The normal procedure to determine the identity or differences between two compounds consists of determining mixture melting points and obtaining spectra using the same instruments and solutions having the same solvents and with identical concentrations of the compounds, or performing HPLC individual and mixed chromatograms. Even where two compounds have the same melting point, one can determine whether the two compounds are the same by mixing a small amount of the first compound with a larger amount of the second compound (or vice versa) and taking the melting point of the mixture. If the first and second compounds are the same compound, the mixture melting point will be the same as the melting point of the first and second compounds in isolation from each other. If they are not the same compound, one will act as an impurity in the other and the mixture melting point will be lower and more spread out than the individual melting points of pure first and second compounds. A

solution phase infra-red spectral comparison using the same concentrations, same solvent and same instrument is also an important method for establishing identity of two substances. None of these tests was done by Igarashi et al., who only examined the compound produced by TP-A0860. As noted above, there was also no direct NMR comparison. No chromatographic comparisons were made either. Without a direct comparison of the compound produced by *Micromonospora* species strain M990-6 (characterized by Ohkuma et al.) and the compound produced by strain TP-A0860 (characterized by Igarashi et al.) by either one or both of these methods, **the assertions** alleged by Igarashi et al. that the two compounds are the same, and that the structure reported by Ohkuma et al. is in error, **are not scientifically convincing or even reasonably supported**.

8. In summary, in my expert opinion, given the significant and striking differences in the NMR spectral data reported by the respective parties, and the absence of any direct comparison versus authentic BU-4664L, I cannot agree that the re-assignment of structure for BU-4664L proposed by Igarashi et al. is valid. In my expert opinion, the reasonable conclusion, given the data available, is that Ohkuma et al. correctly determined the structure of the compound, BU-4664L, which they produced using *Micromonospora* sp. strain M990-6, and that Igarashi et al. correctly determined the structure of a different compound produced by strain TP-A0860. The attempt to force the structure of the compound produced by TP-A0860 onto that produced by M990-6 is not warranted or scientifically supported by the data.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

17 June 2006 — Date

Lester A. Mitscher

CURRICULUM VITAE

LESTER A. MITSCHER

Personal Statistics:

Date of Birth: August 20, 1931
Place of Birth: Detroit, Michigan
Marital Status: Married, three children

Education:

Wayne University, Detroit. 1953, B.S. (Pharm.)
Wayne State University, Detroit. 1958, Ph.D.
(Organic and Physiological Chemistry)
Research Advisor: Professor Carl Djerassi
Dissertation Title: 1) Structure of Cafestol and Khaveol, Coffee Oil Diterpenes, 2) Detection and Stereochemical Implications of Ketal Formation Through Use of Optical Rotatory Dispersion Methods

Fellowships and Honors:

Merck Award (Undergraduate)	1958
National Institutes of Health Predoctorate Fellowship	1955-1958
Phi Lambda Upsilon	1956-1958
Rho Chi	1950-1958
Sigma Xi	1956-1958
Distinguished Alumnus Award, Wayne State University	1976
Research Achievement Award in Natural Products Chemistry, American Pharmaceutical Association/Academy of Pharmaceutical Sciences	1980
Roland T. Lakey Lectureship Award, Wayne State University	1980
Ernest H. Volweiler Award for Research Achievement, American Association of Colleges of Pharmacy	1985
Higuchi-Simons Award in the Biomedical Sciences, Kansas University	1986
Edward E. Smissman Award in Medicinal Chemistry, American Chemical Society,	1989
Elected Fellow, American Association for the Advancement of Science	1995
Distinguished Alumnus Award, Wayne State University, College of Pharmacy	1997
Award in Medicinal Chemistry, Division of Medicinal Chemistry, ACS	2000
Elected Fellow, International Union of Pure and Applied Chemistry	2002

Memberships:

American Chemical Society
British Chemical Society
American Society for Pharmacognosy

American Association for the Advancement of Science
American Society for Microbiology
Japanese Antibiotics Association

Positions Held:

Research Scientist in Microbial Products, Lederle Laboratories	1958-1959
Research Scientist in Alkaloid Chemistry, Lederle Laboratories	1959-1961
Group Leader in Antibiotics and Microbial Products, Lederle Laboratories	1961-1967
Associate Professor of Natural Products Chemistry, The Ohio State University	1967-1969
Professor of Natural Products Chemistry, The Ohio State University	1969-1975
University Distinguished Professor, Department of Medicinal Chemistry, The University of Kansas	1975-date
Chairman, Department of Medicinal Chemistry, The University of Kansas	1975-1991
Intersearch Professor, Victorian College of Pharmacy, Melbourne, Australia	1975-2000
Adjunct Professor of Medicinal Chemistry, University of Missouri, Kansas City	1987-date
Adjunct Professor of Molecular Biosciences, University of Kansas	1995-1999
Chief Scientific Officer, Panax Laboratories, New York, NY and St. Petersburg, Russia, CIS.	1995-1997
Consultant, Abbott Laboratories	1968-date
Consultant on Antitumor Agents, Adria Laboratories	1976-1984
Consultant on Medicinal Chemistry, INTERx Corporation	1976-1980
Consultant on Medicinal Chemistry, G. D. Searle and Co.	1981-2004
Senior Advisory Council, G. D. Searle and Co.	1983-1987
Consultant on Medicinal Chemical Syntheses, W. R. Grace	1985-1986
Consultant on Medicinal Chemistry, Proctor & Gamble	1986-1988
Consultant on Drug Toxicology, Sandoz Laboratories	1992
Consultant on Medicinal Chemistry, DuPont Merck Labs. SAB also	1990- 1995
Consultant on Drug Synthesis, Oread Laboratories	1988-1995
Consultant on Antitubercular Drugs, PathoGenesis Laboratories	1993-1999
Consultant on Combinatorial Chemistry, Pan Laboratories	1994-1997
Consultant on Combinatorial Chemistry, Selectide Corp.	1994
Consultant on Medicinal Chemistry, Geron Corporation	1995-1997
Consultant on Antibiotic Chemistry, Paratek, Inc.	1997-1998
Consultant on Antiinfectives, Cubist, Inc.	1996-1997
Consultant on Natural Products Chemistry, Phyterra, Inc.	1996-2002
Consultant on Medicinal Chemistry, CytoMed, Inc.	1997-2000
Member, Scientific Advisory Board, Small Molecule Therapeutics	1997-2000
Member, Research Advisory Board, XeChem Laboratories	1994-1998
Scientific Advisory Board Member, NeoGenesis, Inc.	1997-2002

Consultant on Cosmaceuticals, Cellegy Corp. SAB 1997-1998
Member, Medicinal Chemistry Study Section B, National Institutes of Health, 1976-1980
Chairman, Biological and Natural Products Study Section, National Institutes of Health, USA 1981-1984
Member, American Cancer Society, Hematology and Chemotherapy Study Section (Chairman, 1989-1991) 1987-1991
Member International Organization for Chemistry in Development (Chairman, Cooperative Drug Screening Program 1986-1994, Medicinal Chemistry Section 1996-) 1986-date
Member, International Union of Pure and Applied Chemistry, 1991-1998
Medicinal Chemistry Division Committee, Chairman of Commission on Education; Associate Member, Commission on Training and Development 1998-date
Member, Board of Directors, XeChem Laboratories 1994-1997
Member, Board of Technical Advisors, Southern Research Institute 1994-2001
Member, Board of Directors, Winter Conference on Bioorganic and Medicinal Chemistry, Vice President. 1994-date
Member, Board of Scientific Advisors, Equataf Phytopharmaceuticals, 1995-2001
Member Scientific Advisory Board, Pharmanex/NuSkin 1995-date
Consultant on Medicinal Chemistry, Versacor 1997-1998
Member of Scientific Advisory Board, Curagen 1998
Member Scientific Advisory Board, Entropin 1998-2000
Consultant in Medicinal Chemistry, RiboGene, Inc. 1998-2001
Consultant in Medicinal Chemistry, Affymax Resarch Institute 1998-2001
Consultant on Neurochemistry, NeuroMed, Inc. (SAB) 1998-date
Consultant on Natural Products Chemistry, Ontogeny, Inc. 1998-2001
Consultant on Medicial Chemistry and Combinatorial Chemistry, Ligand 1998-2001
Consultant on Medicinal Chemistry, Scriptgen/Anadys 1999
Member Scientific Advisory Board, Sequoia 1999-2000
Consultant on Anticancer Agents, CellPath/Primecyte 2000-2003
Member Scientific Advisory Board, Ricerca 2000-2004
Consultant on Medicinal Chemistry, Cumbre, Inc. (SAB) 2003-date
Member Scientific Advisory Board, Forbes MediTech 2002-2006
Consultant on Medicinal Chemistry, Synthon 2002-2003
Consultant on Medicinal Chemistry, ProQuest, Inc. (SAB) 2002-2004
Consultant on Antiviral Agent Chemistry, Rigel 2002
Scientific Advisory Board Member on Medicinal Chemistry, Cambrex Corp.2002-2003
Scientific Advisory Board Member, ICOS Corp. 2001-2002
Consultant on Medicinal Chemistry, Scios, Inc. (SAB) 2002-2004
Consultant on Medicinal Chemistry, Sunesis Corp. (SAB) 2002-date
Consultant on Medicinal Chemistry, ImClone 2004
Member, Drug Discovery and Mechanisms of Antimicrobial Resistance StudySection, NIH 2004-2007

Member, State Board Healing Arts of Kansas,	2003-date
Consultant on Formulations. American Pharmaceutical Partners	2004
Consultant on Medicinal Chemistry, FibroGen, Inc.	2004
Consultant on Medicinal Chemistry, Optimers Pharmaceuticals	2004-
Consultant on Medicinal Chemistry, Sandoz, Inc.	2005-
Consultant on Medicinal Chemistry, Mylan Pharmaceuticals, Inc.	2005-
Consultant on Medicinal Chemistry, Galileo Pharmaceuticals	2005-
Consultant on Antimicrobial Resistance, Achaogen, Inc.	2006
Consultant on Medicinal Chemistry, Warner-Chilcott	2005-

Expert Witness Service:

Adriamycin (Adria* vs Bristol-Myers and Kyowa Hakko)
Ciprofloxacin (Baeyer* vs Ranbaxy)
Ciprofloxacin (Baeyer* vs Barr)
Ciprofloxacin (Baeyer* vs Apotex)
Diltiazem (Hoechst Marion Roussel* vs American Cyanamid)
Doxycycline (International Rectifier/Rachelle Laboratories* vs Pfizer)
Doxycycline (Pfizer vs Rachelle Laboratories* - in Sweden and Austria)
Enalapril (Merck* vs Nu-Pharm)
Fluconazole (Pfizer vs Novopharm*) Settled
Gatifloxacin (Bristol Myers Squibb vs Undisclosed*)
Levofloxacin (Mylan vs Johnson&Johnson/Daiichi)
Lisinopril (Merck vs undisclosed)
Omeprazole (Astra* vs Undetermined as yet)
Taxol (Heuser vs NaPro - I am a special master in this case)
Trovafloxacin (Abbott* vs Pfizer)
Pharmaceuticals (Paul, Hastings, Janofsky and Walker)
Pharmaceuticals (Wiley, Rein & Fielding)
Piperine (Sabinsa vs Naturex*)
Pharmaceuticals (Darby and Darby)
Rispiridone (Mylan vs. Janssen)
Pharmaceuticals (Bennett Jones; Canada)
Pharmaceuticals (American Pharmaceutical Partners)
Sandoz Laboratories vs undisclosed as yet

Elective National Offices Held:

Vice Chairman, Medicinal Chemistry Division, American Chemical Society	1972-1973
Chairman, Medicinal Chemistry Division, American Chemical Society	1973-1974
Councillor, Medicinal Chemistry Division, American Chemical Society	1978-1982
Vice Chairman, American Society for Pharmacognosy	1991-1992
Chairman, American Society for Pharmacognosy	1992- 1993

Editorships:

Allergy and Infectious Diseases	1968-1971
Antimicrobial Agents and Chemotherapy	1971-1974
The Journal of Antibiotics	1973-date
Heterocycles	1973-date
Saudi Journal of Pharmaceutical Sciences	1992-date
The Journal of Medicinal Chemistry	1994-1999
Bioorganic & Medicinal Chemistry Letters	1994-1999
Bioorganic & Medicinal Chemistry	1994-1999
The Journal of Natural Products	1995-1999
Combinatorial Chemistry & High Throughput Screening	1997-date
Medicinal Research Reviews (Editor-in-Chief)	1996-1998
Medicinal Research Reviews (Contributing Editor)	1998-date
Molecules Online	1997-2000
Current Drugs Advisory Board	1998-date
Current Drug Targets - Inflammation and Allergy	2000-2002
Natural Product Letters	2002-date
Current Drug Discovery Techniques	2002-date
Natural Products Research	2004-date
Bioactive Natural Products	2005-date

Books:

The Organic Chemistry of Drug Synthesis. D. Lednicer and L. A. Mitscher. 1977 Wiley Interscience, New York, N.Y. Vol. 1.

The Organic Chemistry of Drug Synthesis. D. Lednicer and L. A. Mitscher. 1979 Wiley Interscience, New York, N.Y. Vol. 2.

The Organic Chemistry of Drug Synthesis. D. Lednicer and L. A. Mitscher. 1984 Wiley Interscience, New York, N.Y. Vol. 3.

The Organic Chemistry of Drug Synthesis. D. Lednicer, G. I. Georg and L. A. Mitscher. Wiley Interscience, New York, N.Y. Vol. 4. 1989

The Chemistry of the Tetracycline Antibiotics. L. A. Mitscher. Marcel Dekker, New York, N.Y. 1978

The Green Tea Book: China's Fountain of Youth. L. A. Mitscher and Virginia Dolby, Avery Press, N. Y. 1997

U.S. PATENTS
(Related foreign patents not listed)

J. D. Albright, L. A. Mitscher, L. Goldman. New derivatives of yohimbe alkaloids. Belg. 611,137 (1962).CA 60:P 14557d (1964).

P. A. Miller, J. H. E. J. Martin, L. A. Mitscher. Novel 5a,6-Anhydrotetracyclines. US 3,265,732 (1966). CA 66:P1587a (1967).

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